

JAN 27 2003

11-1

SECTION 11 – 510(k) SUMMARY**Date of Application:** March 14, 2002**Applicant's Name and Address:**

Acist Medical Systems, Inc.
7450 Flying Cloud Drive
Suite 150
Eden Prairie, MN 55344

Name of Contact Person:

Carl M. Beaurline
Vice President, Quality Assurance / Regulatory Affairs

Telephone and Fax Numbers:

Telephone – (952) 995-9319
Fax – (952) 941-4648

Proprietary Name: Acist GENTOO Contrast Injection System**Common Name:** CT Injection System**Classification Name:** Injector and Syringe, Angiographic**Classification Number:** 870.1650**Class:** II**Classification Panel:** Cardiovascular**Product Code:** DXT**Predicate Devices:**

- Medrad EnVision CT Injection System and Disposable Kit
- Acist CMS2000 Angiographic Injection System Disposable Kits

Device Intended Use:

The **ACIST GENTOO Contrast Injection System for Computed Tomography** is intended for use in the delivery of radiopaque contrast media to selected sites in the vascular system during computed tomography applications.

Device Description:

The ACIST GENTOO is a dual-syringe injector with one contrast syringe and one saline syringe that allows the user to program procedure protocols that specify injection parameters for both contrast and saline, and to allow the technologist to use saline for test injections. The ACIST GENTOO uses a two part injection molded dual syringe kit that incorporates ACIST's Contrast Management System (CMS) technology. The CMS functionality allows the user to disconnect and discard the patient contact portion of the kit at the end of each case, and use the syringe kit for up to 8 cases.

The four basic components of the device are distributed in the user facility between the:

- CT lab [(1) Injector Head and (2) Syringe and Patient Kits] and the
- Control Room [(3) Remote Display and (4) Power Supply] where the CT imaging equipment is operated.

Summary of Comparative Technological Characteristics with Predicate Device:

- Intended Use
- Location of Use
- Weight
- Operating/Non-Operating Environmental Specifications
- Protection Against Electrical Shock
- Current Leakage and Continuity
- Fluid Delivery Performance
- Flow Rate Range
- Pressure Limit Parameters
- Autofill Parameters
- Test Inject Parameters
- Pause and KVO Parameters
- Scan Delay Parameters
- Syringe Heater Parameters
- Safety Features

Summary of Comparative Performance Testing with Predicate Device To Demonstrate Substantial Equivalency:

- Fluid Delivery Volume Range
- Fluid Delivery Volume Accuracy
- Flow Rate Range Accuracy
- Flow Rate Range Duration
- Pressure Limit Range
- Pressure Limit Accuracy
- Autofill Volume Range
- Autofill Fill Rate Default
- Autofill Fill Rate Range
- Test Injection Fluids
- Test Injection Default
- Test Injection Flow Rate Range
- Test Injection Volume Range
- Test Injection Volume Accuracy
- Pause Range
- Pause Accuracy
- KVO Flow Rate
- KVO Volume Accuracy
- Scan Delay Time Range
- Scan Delay Time Accuracy
- Syringe Heater Average Fluid Temperature



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 27 2003

Mr. Carl M. Beaurline
Vice President, QA/RA
ACIST Medical Systems, Inc.
7450 Flying Cloud Drive, Suite 150
Eden Prairie, MN 55344

Re: K020892
Trade/Device Name: Acist GENTOO Contrast Injection System
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic injector and syringe
Regulatory Class: Class II
Product Code: DXT
Dated: November 6, 2002
Received: November 7, 2002

Dear Mr. Beaurline:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

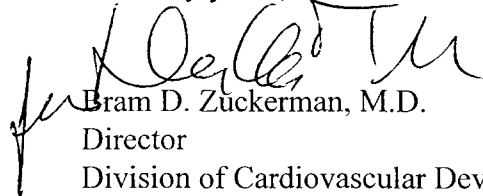
Page 2 – Mr. Carl M. Beaurline

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Bram D. Zuckerman', is written over the typed name.

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

INDICATIONS FOR USE FORM

Page ____ of ____

510(k) Number: K020892Device Name: **Acist GENTOO Contrast Injection System**

Indications for Use:

The Acist GENTOO Contrast Injection System for Computed Tomography is intended for use to deliver radiopaque contrast medium to selected sites in the vasculature during computed tomography applications.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____
(Optional Format 1-2-96)


(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K020892